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THE VIEWS EXPRESSED IN THIS ARTICLE ARE THOSE OF THE AUTHOR AND DO NOT REFLECT THE OFFICIAL POLICY OR POSITION OF THE UNITED STATES AIR FORCE, DEPARTMENT OF DEFENSE, OR THE U.S. GOVERNMENT.

Endotracheal Tube Cuff Pressure Following Intubation

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Endotracheal Tube Cuff Pressure Following Intubation

Abstract

An endotracheal tube (ETT) is frequently necessary for airway management. Proper inflation of the ETT cuff is critical for patient safety. Pressure must be high enough to seal the trachea to prevent aspiration of regurgitated stomach contents and avoid air leaks to the atmosphere, yet low enough to allow adequate perfusion of the tracheal mucosa.

This study explored the anesthesia provider's ability to correctly determine ETT cuff pressure using a qualitative estimation (finger palpation of the ETT pilot balloon) compared to a quantitative measurement (manometer). The hypothesis was that there would be a difference between the two assessments.

After patient intubation, an anesthesia provider inflated the ETT cuff to their estimated appropriate pressure by finger palpation of the pilot balloon. A researcher then obtained a quantitative measurement of the actual pressure using a manometer. Data was obtained from fifty patients and the qualitative and quantitative measurements were compared.

Overall, seventy two percent of the cuff pressures were incorrectly estimated by finger palpation (26% too low, 46% too high). Findings confirm that the qualitative method of ETT cuff pressure measurement is both a less precise and inconsistent means for determining actual pressure than is quantitative measurement and may compromise patient safety.

Introduction

Endotracheal intubation is one of many airway adjuncts used during general anesthesia. The Arabian doctor Avicenna (980-1037) described the first orotracheal intubation for dyspnea.[1] Approximately 900 years passed between the first intubation and the development of a cuffed ETT. G. M. Dorrance, M.D., a surgeon, described the earliest cuffed tube for management of patients with thoracic and pulmonary injuries in 1910.[2] In 1928, Ralph M. Waters, M.D. and Arthur E. Guedel, M.D. introduced what they believed to be a new type of endotracheal tube with an inflatable rubber cuff that could seal the trachea from gas and water when inflated for anesthetic purposes.[3]

The process of endotracheal intubation has had approximately 1000 years to evolve into a safe practice, but over inflation of the ETT cuff continues to be a cause of irreversible damage to the tracheal mucosa. Undetected over-inflation of the ETT cuff balloon may disrupt the capillary blood supply leading to ischemia, pressure induced lesions, nerve and vocal cord damage. Under-inflation may lead to aspiration or the inability to provide positive pressure ventilation. Ideal pressure of the ETT cuff is sufficient to seal the trachea, prevent aspiration of regurgitated stomach contents, and avoid air leaks to the atmosphere while still allowing adequate blood flow to the tracheal mucosa.

Problems associated with ETT intubation can be attributed to factors such as ETT size, patient airway size, lateral tracheal wall mucosa pressure, and

movement of the ETT. Specifically, ETT cuff related tracheal damage is mostly influenced by duration of intubation and/or excessive lateral tracheal wall pressure; of the two factors, pressure is more important.[4]

The tenets of the Starling hypothesis state that capillary wall filtration is an intricate balance between two pressure gradients. This balance is maintained by the opposing forces along the capillary caused by the hydrostatic and osmotic pressure of the capillaries and interstitium. Movement of fluid and nutrients from the arteriole to the venous end of the capillary is due to hydrostatic and osmotic pressure gradients. This delicate balance of movement may be interrupted by pressure placed upon the tissue. The capillary perfusion pressure at the tracheal mucosa is 25-35 millimeters of mercury (mm Hg) or 34-48 centimeters of water (cm H_2O).[5] The ideal ETT cuff pressure to allow optimal perfusion yet provide adequate airway protection is 20-25 mm Hg (27-34 cm H_2O).[6] This provides a very small window to maintain airway protection while avoiding increased mucosal contact pressures with an inflated ETT cuff.

Elevated mucosal pressure, as produced by over-inflated ETT cuffs, represents an increase in tracheal tissue pressure. This pressure change may lead to an obstruction of the capillary hydrostatic pressure and produce an increase in salt and fluid retention leading to edema.[7] The formation of edema in the trachea in response to increased ETT cuff pressure can be of significance post-operatively. The full appreciation of swelling may not be apparent at extubation

but may become troublesome when the patient arrives in the post anesthesia care unit or back in their room. Mucosal contact pressure, which may not appear excessive during the short term, may depress mucosal perfusion sufficiently such that the prolonged cumulative effects of ischemia result in serious mucosal and tracheal injury.[8] Delayed swelling may lead to airway obstruction or result in tracheal stenosis.

Insertion of an ETT into the trachea produces minor superficial damage to the tracheal epithelium while extreme over-inflation of an ETT cuff to 100 mm Hg (136 cm H_2O) can disrupt the tissue to the level of the basement membrane.[9] After ETT insertion, the measurement of cuff pressure has historically been performed by qualitative finger palpation in which the anesthesia provider squeezes the pilot balloon between their forefinger and thumb to judge the amount of pressure in an inflated ETT cuff. This method may lead to erroneous cuff pressures.

Fernandez, Blanch, Mancebo, Bonsoms, and Artigas studied the accuracy of estimation of ETT cuff pressure using finger palpation. They hypothesized that qualitative finger palpation could misjudge the appropriate inflation pressure due to the different characteristics of the ETT components used by different manufacturers. Their results showed that the ETT cuff pressure estimated by the anesthesia providers was frequently different, either too high or too low, from the actual pressure of the ETT cuff.[10]

A more recent study from the University of Tennessee at Chattanooga compared ETT cuff pressures using estimation techniques and direct intracuff measurement. Their results revealed that 70% of the estimated ETT cuff pressures were outside the ideal range. Of that 70%, ETT cuff pressures were elevated in 65% of the patients and too low in 5%.[11]

This study attempts to build upon previous work by strengthening the design to eliminate several variables that could potentially confound the results. Previous research utilized first and second year nurse anesthesia residents, while this study specifically excluded them due to their lack of experience and allowed only fully certified practitioners to participate. A manometer that had a range of only 0-60 cm H_2O, effectively truncating the upper pressure range and potentially skewing the results, limited measurement of maximum pressure in previous studies. This study used the Posey Cufflator™ Tracheal Cuff Inflator and Manometer with a full range of 0-120 cm H_2O.

Cuff pressures in previous studies were not measured within any specific time frame and subjects were allowed to receive nitrous oxide (N_2O). The diffusion of N_2O into the ETT cuff causing increased ETT pressure over time has been documented in many studies.[4,12,13,14] Most definitively, Tu, et al. studied the effects of N_2O on ETT cuff pressure. They were able to demonstrate that ETT cuffs filled with air expanded slowly with N_2O use during anesthesia increasing pressure on the tracheal mucosa.[12] These potentially significant problems were

controlled in this study by excluding subjects receiving N_2O and measuring all pressures immediately after intubation.

Purpose of study

The purpose of this research study was to assess if anesthesia providers could accurately measure ETT cuff inflation pressures by using the currently practiced method of finger palpation. The hypothesis was that there would be a difference between qualitative estimation and quantitative assessment of ETT cuff pressure. Findings of consistent improper inflation of the ETT cuff above the allowable maximal tracheal capillary perfusion pressure or below the protective airway pressure may demonstrate the need to mandate use of quantitative measures as standard of care for the assessment of ETT cuff inflation. The specific research questions for this study were as follows:

1. What is the occurrence rate of inappropriate pressure within ETT cuff balloon after initial inflation?
2. What is the range of the actual inflation pressures and do they fall within the defined acceptable limits to maintain adequate tracheal capillary perfusion pressure while ensuring adequate ventilation?
3. Is there a relationship between qualitative and quantitative ETT cuff inflation pressures?

Materials and methods

The sample size was projected based on results from previous studies using an estimated effect of 1.0, alpha of .05, and power of .80. The minimum required sample size was estimated to be 30 subjects. Fifty subjects were targeted for enrollment to ensure an adequate sample size.

Institutional Review Board approval was obtained prior to the initiation of data collection. Two groups of subjects were consented for this study: anesthesia providers and the patients to which these anesthesia providers were assigned.

Inclusion criteria for providers required completion of their formal anesthesia training. This meant that nurses were required to be Certified Registered Nurse Anesthetists (CRNA) and physicians were required to have completed their residency in anesthesia and be either board certified or board eligible as Anesthesiologists. Physician and nurse anesthesia residents were excluded due to their lack of experience.

Patient inclusion criteria were as follows: (1) age 18 years or older; (2) orally intubated with a Mallinckrodt high-volume, low-pressure ETT; (3) non-emergent case; and (4) consent to participate. Exclusion criteria were the (1) the use of N_2O before ETT cuff measurement and (2) nasal intubation. Nasal intubations were excluded due to the significantly different type of ETT used.

Patients were consented on a daily basis as they met the inclusion criteria and agreed to participate. Providers were blinded as to when measurements would

take place and which patients were consented. The data collection instrument included the level of training of the anesthesia provider accomplishing intubation, years of experience of the provider, time elapsed after intubation before measurement was taken, verification that N_2O was not used, amount of air in cubic centimeters (cc) used to inflate the ETT cuff, the providers qualitative estimation of ETT inflated cuff balloon pressure, and the actual cuff pressure as measured by the manometer. Patient and provider identifiable data was not included on the data collection tool.

Actual cuff pressures were measured using the Posey Cufflator™ Tracheal Cuff Inflator and Manometer. The range of the manometer gauge is between zero and 120 cm H_2O. This range ensured that ETT cuff pressures severely outside the safe range could be noted. The manometer was tested and verified by the hospital Medical Equipment Repair Center (MERC) to ensure accurate measurement. It was determined to be accurate to within ±2 cm H_2O.

Research team members trained in the study protocol accomplished the collection of data. Upon the patient's arrival in the surgical suite, the anesthesia provider was allowed to intubate the patient and inflate the cuff per their normal standard of care (qualitative assessment). Providers were blinded as to which patients had consented to enrollment. Research team members then entered the OR suite, and obtained a quantitative measurement of the ETT cuff inflation pressure using the manometer. All study data was recorded and adjustments were

made to the cuff if necessary to bring the ETT cuff into the acceptable inflation range.

Statistical analyses for descriptive and inferential statistics were performed using SPSS for Windows 12.01 (SPSS, Inc., Chicago, IL). Level of significance was set at $p \leq .05$ for all tests unless a lower level was indicated as being substituted for statistical stringency.

Results

Twenty-five anesthesia providers and 50 patients consented to participate. Anesthesiologists performed 10 of the ETT cuff pressure measurements, while CRNA performed the remaining 40. Eight of ten (80%) anesthesiologists' measurements were by providers with 0-4 years experience; 1 (10%) with 5-9 years; and 1 (10%) with more than 15 years work experience. Twenty of forty (50%) measurements obtained by a CRNA were by providers with 0-4 years experience; 5 (12.5%) with 5-9 years; and 15 (37.5%) with 10-14 years experience. Spearman's correlation was performed to determine if the providers' years of experience had any bearing on their ability to adequately determine proper ETT cuff pressure. No association was found between the two variables ($r = ^{-} 0.002$, $p = .991$).

The participating patients were selected from a convenience sample of patients undergoing elective surgery. Of the 50 patients in the study, 24 (48%) were male and 26 (52%) were female.

The mean amount of air injected was 7 cc and ranged from as little as 2 cc to as much as 12 cc. The actual measured pressures ranged from 11 to 110 cm H_2O. Mean pressure was 42.18 cm H_2O (SD +/- 25.38), the mode and median were 32 cm H_2O. All of the providers predicted the ETT cuff measurement would be within the acceptable range, yet 36 of 50 measurements (72%) were not within the specified limit of 27-34 cm H_2O. Overall, 28% (14) of the ETT cuff pressures were within the acceptable limits, with 26% (13) lower than estimated/acceptable and 46% (23) higher than estimated/acceptable (Figure 1).

One (10%) of the anesthesiologist's measurements was within the acceptable range, while 13 (32.5%) of the CRNA measurements were correct. The Pearson's correlation coefficient did not indicate a statistical significant relationship between the actual ETT cuff pressures and the anesthesia provider's estimate of the pressure ($r = 0.074$, $p = .255$).

A chi-square test of independence was performed to determine if there was a relationship between type of provider (anesthesiologist or CRNA) and having an ETT cuff pressures within the prescribed range. The analysis yielded a X^2 value of 2.009 ($df = 1$, $p = .156$) indicating no relationship between the provider type and correct inflation pressure.

Patient size and tracheal diameter may have an effect on the provider's ability to correctly estimate cuff pressures. Data was assessed to determine if there was any relationship between patient size and cuff inflation pressures. The

patient's weights ranged from 58-148 kilograms (kg) with the mean weight of 83 kg (SD +/- 18.9). Pearson's correlation coefficient revealed there was no significant relationship between the patient's weight and the actual measured cuff pressure ($r = 0.067$, $p = .261$).

Discussion

Erroneous ETT cuff pressure seems to be a current and ongoing problem that has generated a significant body of varied literature. A significant amount of the research demonstrated the significance of N_2O on ETT cuff pressure intra-operatively.[4,12,13,14] However, there are few research studies exclusively devoted to initial ETT cuff inflation pressures. The focus of this study was to ascertain the anesthesia provider's ability to accurately determine initial ETT cuff pressure using finger palpation of the pilot balloon.

Operator error has been implicated due to the method used by anesthesia providers to determine cuff pressure. Typically, digital manipulation of the inflated pilot balloon between the forefinger and thumb is the current accepted practice to measure ETT cuff pressure. This estimation is completely dependent upon provider judgment. Multiple previous studies have demonstrated that the finger palpation method is not a consistent method to determine ETT pressure and avoid intra-operative tracheal mucosal damage.[7,9,10,11,15,16] Finger palpation yields incorrect inflation pressures a majority of the time. The variability of actual ETT cuff pressure compared to one's estimation of ETT cuff pressure identifies a

knowledge and skill deficit. These deficits demonstrate the necessity of education to minimize potential harm to the patient.

This research study confirms that the qualitative method of ETT cuff pressure measurement is a less precise and inconsistent means for determining actual pressure than quantitative measurement. Therefore, this suggests that quantitative measurement of ETT cuff pressure following initial intubation should be considered as a standard of practice for any provider that performs endotracheal intubation.

The methodology of this study has several limitations. The study population consisted entirely of patients scheduled for elective surgical procedures at a single facility. The investigation excluded any patient less than 18 years of age, requiring an emergent procedure, given N_2O during induction, or who were nasally intubated. Trials including these patients may potentially have different findings.

A future recommendation would be to guide anesthesia providers through a classroom practicum where they will actively participate in measuring ETT cuff pressure with a manometer on an endotracheal model. Immediate feedback on actual versus qualitative ETT cuff pressure should increase awareness and enhance future performance.

Summary

The goal of this study was to explore the accuracy of determining ETT cuff pressure via the qualitative finger palpation method in comparison to the quantitative measurement with a manometer. Seventy two percent of 50 ETT cuff pressures were out of the safe range suggesting a need for the use of a more accurate method of measuring ETT cuff pressure. This research supports previous studies that show estimation of ETT cuff pressure utilizing the finger palpation method is inaccurate.

It has been roughly 1000 years since the first description of orotracheal intubation. Perhaps it is time for a definitive statement regarding a standard of practice for quantitative measurement of ETT cuff pressures following initial intubation.

Acknowledgements

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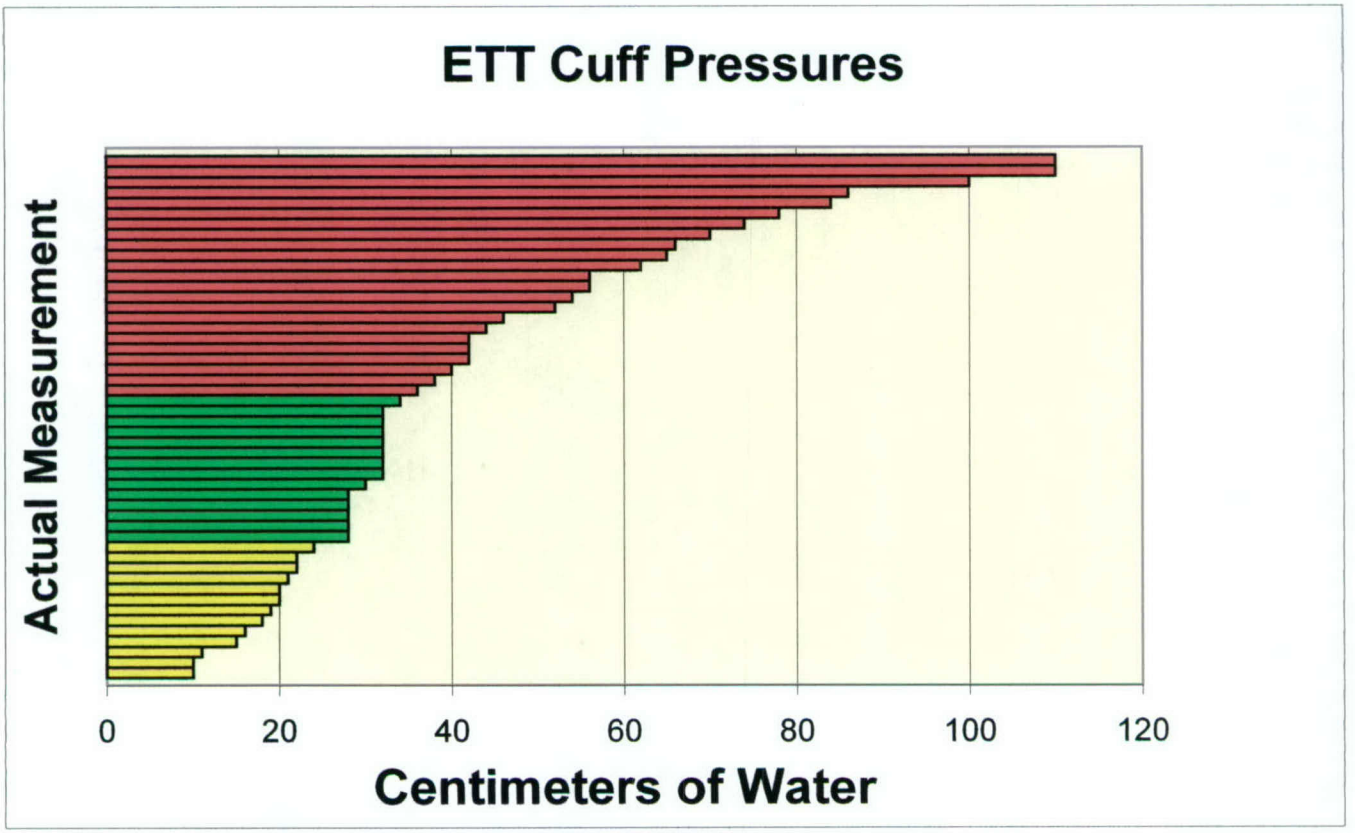
Figure and Table Legend

Figure 1: Range of ETT Cuff Pressure

Appendix

Figure 1 **Range of ETT Cuff Pressure**



Red: >34 cm H_2O
Green: within 27 – 34 cm H_2O
Yellow: <27 cm H_2O

DEPARTMENT OF THE AIR FORCE
74TH MEDICAL GROUP
WRIGHT-PATTERSON AIR FORCE BASE, OHIO

7 September 2004

MEMORANDUM FOR 74 MSGS/SGCJ
ATTN: CAPT MICHAEL POWELL

FROM: 74th MDOS/SGOA
Clinical Investigations
4881 Sugar Maple Drive
WPAFB OH 45433-5529

SUBJECT: Notification of Protocol Approval

1. The Clinical Investigation protocol you submitted, FWP20040026H, "Endotracheal Tube Cuff Pressure Following Intubation," and consent document have been reviewed and approved by the WPMC Institutional Review Board and the WPMC Deputy Commander. Once USUHS approves your protocol you may begin this study.

2. As an investigator you will be required to submit all amendments to Clinical Investigations prior to implementation, report study progress annually (first one due in August 2005), report any unanticipated major adverse reactions or medical misadventures (local or regional), and comply with the Certificate of Compliance (attached) which was submitted with your protocol. Failure to meet all requirements may lead to suspension or termination of your protocol.

3. When you are ready to begin enrolling patients, please contact me at (937) 257-4242 and let me know how many consent form packages you will need. I hope that your study will prove to be a worthwhile experience for you.

D Bachman

DEBBIE BACHMAN
Clinical Investigations Coordinator

Attachment:
Certificate of Compliance

DEPARTMENT OF THE AIR FORCE
88th MEDICAL GROUP
WRIGHT-PATTERSON AIR FORCE BASE OHIO

11 January 2005

MEMORANDUM FOR 88 MSGS/SGCJ
ATTN: CAPT MICHAEL POWELL

FROM: 88 MDSS/SGSF
Clinical Investigations Office
4881 Sugar Maple Drive
Wright-Patterson AFB OH 45433-5529

SUBJECT: Clinical Investigation Protocol Amendment (ICD Revision)

1. On 7 January 2005 the WPMC Institutional Review Board approved the item(s) listed below (via expedited review) which you submitted for review :

FWP20040026H, "Endotracheal Tube Cuff Pressure Following Intubation," P.I. Capt Michael Powell/SGCJ. Reviewed/approved ICD revision reflecting facility name change from 74th Medical Group to 88th Medical Group.

2. If you have any questions, I can be reached at 74242.

DBachman
DEBBIE BACHMAN
Clinical Investigations Coordinator
Wright-Patterson Medical Center

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November 29, 2004

MEMORANDUM FOR CAPT MICHAEL POWELL, SRNA, GRADUATE SCHOOL OF NURSING

SUBJECT: Uniformed Services University Institutional Review Board Approval (FWA 00001628) of T061FD for Human Subject Participation

Congratulations! Your minimum risk research protocol T061FD, entitled "Endotracheal Tube Cuff Inflation Pressure following Intubation," was reviewed and approved for execution on November 29, 2004 by Edmund G. Howe, M.D., J.D., Chairperson, Institutional Review Board, under the provisions of 32 CFR 219. **This approval expires on November 28, 2005.** You are authorized to enroll up to 100 subjects in this study. This approval will be reported to the full Uniformed Services University IRB scheduled to meet on December 16, 2004.

The purpose of this study is to assess if the currently accepted subjective method of finger palpation is an appropriate measurement for initial estimation of ET cuff inflation pressure in relationship to a quantitatively obtained pressure using a manometer. This protocol evaluates the anesthesia provider's ability to accurately estimate ET balloon pressures. The incidence and degree of inaccurate pressures within the ET cuffs will include two criteria: the occurrence of inappropriate pressure within ET cuffs and the range of the actual inflation pressure after intubations.

IRB authorization to conduct this protocol will automatically terminate on November 28, 2005. If you wish to continue data collection or analysis beyond this date IRB approval for continuation is required. Please submit a USU Form 3204A/B (application for continuing approval) to the Office of Research by **September 29, 2005**. Though we will attempt to assist you by sending you a reminder, submission of an application for continuation is your responsibility. *Please note the termination date and the date for submission of your USU Form 3204 in your calendar!*

You are required to submit amendments to this protocol, changes to the informed consent document (if applicable), adverse event reports, and other information pertinent to human research for this project to this office for review. No changes to this protocol may be implemented prior to IRB approval. If you have questions regarding specific issues on your protocol, or questions of a more general nature concerning human participation in research, please contact me at 301-295-0814/9534 or abraziel@usuhs.mil.

Andrew J. Braziel
Institutional Review Board Coordinator

cc: Director, Research Administration
Chair, GSN
File
Ms. Shohreh Razi, GSN

Learning to Care for Those in Harm's Way

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November 29, 2004

MEMORANDUM FOR CAPT MICHAEL POWELL, SRNA, GRADUATE SCHOOL OF NURSING

SUBJECT: Uniformed Services University Institutional Review Board Approval (FWA # 00001628) of Amendment to T061FD

The amendment to your protocol T061FD, entitled "*Endotracheal Tube Cuff Inflation Pressure following Intubation,*" was reviewed and approved for execution on January 7, 2005 by Edmund G. Howe, M.D., J.D., Chairperson, Institutional Review Board, under the provisions of 32 CFR 219.110(b)(2). You are authorized to enroll up to 100 subjects in this study. This approval will be reported to the full Uniformed Services University IRB scheduled to meet on March 10, 2005.

The purpose of this study is to assess if the currently accepted subjective method of finger palpation is an appropriate measurement for initial estimation of ET cuff inflation pressure in relationship to a quantitatively obtained pressure using a manometer. This protocol evaluates the anesthesia provider's ability to accurately estimate ET balloon pressures. The incidence and degree of inaccurate pressures within the ET cuffs will include two criteria: the occurrence of inappropriate pressure within ET cuffs and the range of the actual inflation pressure after intubations.

Wright-Patterson Medical Center has recently changed its designation from the 74th Medical Group to the 88th Medical Group. This change is noted in the letterhead in both the resident and patient informed consent documents (ICDs). New ICDs were provided to the USUHS and Wirght-Patterson IRBs.

Authorization to conduct this protocol will automatically terminate on November 28, 2005. If you plan to continue data collection or analysis beyond this date IRB approval for continuation is required. Please submit a USU Form 3204A/B (application for continuing approval) to the Office of Research by **September 29, 2005**. Though we will attempt to assist you by sending you a reminder, submission of an application for continuation is <u>your</u> responsibility. ***Please note the termination date and the date for submission of your USU Form 3204 in your calendar!***

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Andrew J. Braziel
Institutional Review Board Coordinator

cc: Director, Research Administration
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